



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JUN 18 1999

4102 '99 JUN 21 A9:53

Mr. Dennis M. Gronek
Gronek & Armstrong
98th Floor - Sears Tower
233 South Wacker Drive
Chicago, Illinois 60606

Dear Mr. Gronek:

This is in response to your letter of June 14, 1999 to the Food and Drug Administration (FDA) on behalf of Natrol, Inc. pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)). In your letter, you state that Natrol, Inc. is making the claims "Promotes balanced cholesterol levels" and "Red Yeast Rice-Extract has been shown in human studies to play a major role in promoting healthy cholesterol levels" for the product CholesterSure. This product contains the ingredient red yeast fermented on rice, which is generally prepared using *Monascus purpureus*.

This letter is to advise you of the current status of products that contain red yeast rice. FDA announced its administrative decision on May 20, 1998 that a product named "Cholestin¹", manufactured by Pharmanex, Inc., which was promoted as a dietary supplement intended to affect cholesterol levels, is not a dietary supplement, but is instead an unapproved drug under the FD&C Act. This decision meant that Cholestin could not be legally sold in the United States.

On February 16, 1999, the United States District Court for the District of Utah "held unlawful and set aside" the FDA's administrative finding of May 20, 1998. FDA has appealed the District Court's decision to the United States Court of Appeals for the 10th Circuit. The future regulatory status of all red yeast rice products will depend, in part, on the decision of the courts on the merits of the Cholestin matter. At this time, FDA believes that products containing red yeast rice or *Monascus purpureus* that contain lovastatin are unapproved new drugs that are in violation of the FD&C Act.

¹Cholestin consists of the yeast *Monascus purpureus* when fermented on premium rice powder. The fermentation of the rice with this yeast, under certain conditions, produces a product that contains lovastatin, the active ingredient in the prescription cholesterol-lowering drug Mevacor.

975-0163

LET282

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Please contact us if we may be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read 'Lynn A. Larsen', with a long horizontal flourish extending to the right.

Lynn A. Larsen, Ph.D.

Director

Division of Programs and Enforcement Policy

Office of Special Nutritionals

Center for Food Safety

and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

**FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200**

FDA, San Francisco District Office, Office of Compliance, HFR-PA140

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605 (Bowers)

GCF-1 (Dorsey, Barnett, Nickerson, Parker)

HFV-228 (SBenz)

f/t:HFS-456:rjm:6/17/99:docname:65693.adv:disc38

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GRONEK & ARMSTRONG

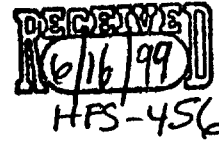
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TEL: (312) 655-1800
FAX: (312) 655-1808

June 14, 1999



Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. S.W.
Washington, D.C. 20204

Re: 21 U.S.C. Section 343(r)(6)
Notification of Statements on Dietary Supplements

Dear Sir/Madam:

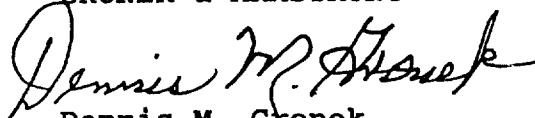
This firm represents Natrol, Inc., Chatsworth, California, a manufacturer of dietary supplement products (hereinafter "NATROL").

On behalf of Natrol, and pursuant to the requirements of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. § 343(c)(6), your Agency is hereby notified that NATROL proposes to make statements of "nutritional support", as described in 21 U.S.C. § 343(1)(6)(A), in the labeling of CholesterolSure, a red yeast-rice extract, as follows:

- (1) Promotes balanced cholesterol levels.
- (2) Red Yeast Rice-Extract has been shown in human studies to play a major role in promoting healthy cholesterol levels.

To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete. NATROL possesses substantiation that the statements are truthful and not misleading.

Sincerely yours,
GRONEK & ARMSTRONG


Dennis M. Gronek

DMG:
pr
CC: Natrol, Inc.